



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

91350d

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

JUN -7 2001

WARNING LETTER

**Certified Mail**  
**Return Receipt Requested**

Gerald T. Wolke, RPh.  
Natural Health Consultants  
BioScan 2010  
P.O. Box 1091  
Vallejo, California 94590

Dear Mr. Wolke:

We are writing you because the Food and Drug Administration (FDA) obtained information from your Internet site, <http://www.naturalhealthconsult.com/Monographs/Bioscan2010.html> that revealed a possible regulatory violation involving BioScan 2010/Ultra Early Biocellular Markers or Biological Terrain Management. These products appear to be manufactured and/or commercially distributed by the North Carolina Institute of Technology.

The website that mentions Bioscan 2010, indicates that the kits are intended to determine long range whether an individual is likely to develop a serious disease. The website also indicates the kits are intended to identify the problems that may cause the disease and how to treat or change those abnormal conditions. Under a United States law, known as the Federal Food, Drug and Cosmetic Act (the Act), these products are considered to be medical devices because they are used in the diagnosis of disease, or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or intended to affect the structure or any function of the body of man, and/or to treat a medical condition.

This law requires that manufacturers of medical devices obtain FDA marketing clearance or approval for their products from the FDA before they can offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective, and will perform as intended/labeled. A

guidance document and labeling requirements for marketing these devices can be found at <http://www.fda.gov/cdrh/ode/.html>.

Our records indicate that you did not obtain marketing clearance or approval before offering your products for sale over-the-counter. If you do not have marketing clearance for your devices it is a violation of a federal law to sell the devices in the U.S. and may result in the FDA taking regulatory action.

Because you do not have marketing clearance from the FDA, marketing your product in this country is a violation of the Act. In legal terms, the product is adulterated under section 501 (f)(1)(B), and misbranded under section 502(o) of the Act. Your product is adulterated under the Act because you did not submit information that shows your device is safe and effective. Also, your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed in this country.

Please provide this office within thirty (30) working days after you receive this letter, with:

- 1) A complete copy of the labeling for your devices (including the product insert and outer package labeling).
- 2) Documents that indicate you have obtained FDA marketing clearance or approval for your devices or purchased such clearance from other firm.
- 3) The name of the manufacturer and address.

You should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to premarket clearance for your devices and does not address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for medical device manufacturers by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or the Internet at <http://www.fda.gov>.

In addition to the Act, you may be subject to Section 5 of the Federal Trade Commission Act (15 U.S.C. § 45), which prohibits deceptive acts or practices in or affecting commerce. Also, Section 12 of the Federal Trade Commission Act (15 U.S.C. § 52)

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prohibits the dissemination of any false advertisement to induce the purchase of any food, drugs, or devices.

If we do not hear from you within 30 days, the FDA will assume that you do not have approval or clearance to market this over the counter products, and will proceed accordingly.

If you have more specific questions about FDA marketing requirements that may affect your devices, or about the content of this letter, please contact Dr. A.Gonzalez-Licea at 301-594-4595 ext. 171

Sincerely yours,

A handwritten signature in black ink, appearing to read "L. D. Spears", with a stylized flourish at the end.

Larry D. Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health